UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: COLGATE-PALMOLIVE SOFTSOAP ANTIBACTERIAL HAND SOAP MARKETING AND SALES PRACTICES LITIGATION (MDL No. 2320)	)))))	MDL Docket No. 12-md-2320-PB ALL CASES

DEFENDANT COLGATE-PALMOLIVE COMPANY'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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Preliminary Statement

Plaintiffs' suit rests on the tenuous premise that Colgate warranted or otherwise represented that Softsoap Antibacterial Hand Soap was more effective than soap without antibacterial ingredients. To the contrary, plaintiffs' allegations make evident that the only relevant representations—that the product is "antibacterial," "kills 99% of germs," is "clinically proven to eliminate 99% of the germs your family encounters," or is "dermatologist tested" — make absolutely no comparative claims. Not only do these statements not support plaintiffs' legal theories, they are also subject to the regulatory authority of the U.S. Food and Drug Administration, which is currently evaluating the safety, efficacy, and labeling of triclosan—the antibacterial ingredient contained in Softsoap Antibacterial. By squarely putting at issue the lawfulness of labeling statements on hand soaps containing triclosan, plaintiffs' Complaint encroaches upon the primary jurisdiction of the FDA. Asking this Court and lay fact finders to decide these issues seeks to sidestep the FDA's almost four decades of expertise, under Congressional mandate, in regulating triclosan.

Allowing this case to proceed also creates the risk of disparate standards regarding the labeling of antibacterial hand soap—not merely from jurisdiction to jurisdiction concerning Softsoap, or among other manufacturers such as Dial or Bath & Body Works, but also with the FDA's overall policies relating to antibacterial agents. This escalates the likelihood of confusing consumers and granting certain companies a competitive advantage regarding the statements they can make about the exact same ingredient. Consistent with the need for national uniformity on this issue, the institutional expertise the FDA has acquired, and its Congressional authority, the FDA has announced it will soon issue regulations that address the very same issues presented by this case. This is precisely the type of action properly dismissed under the doctrine of primary jurisdiction.

Independently, the Complaint fails to state a claim. First, plaintiffs' allegations concerning the implied "message" of Colgate's marketing do not support either a breach of express warranty claim nor a claim under the relevant state consumer-protection laws. (*Infra* § III.A.) Plaintiffs cannot demonstrate any reasonable consumer could be deceived by Colgate's marketing, and in any event, any possible implied statement that Softsoap Antibacterial is "more effective" than conventional soap constitutes mere puffery. Second, plaintiffs do not plausibly allege with supporting facts that Colgate's express statements are false; instead, they pin their causes of action on conclusory allegations that no reliable studies support Colgate's express claims—allegations insufficient to sustain plaintiffs' claims. (*Infra* § III.B.) Third, plaintiffs proffer no reasoning for their implied warranty claims, again resting on conclusory allegations that Softsoap Antibacterial was neither merchantable nor fit for the designed purpose. (*Infra* § III.C.) Moreover, plaintiffs' unjust enrichment theory and injunctive relief "claim" cannot stand because consumers have an adequate remedy at law. (*Infra* §§ III.D, III.E.) Finally, by seeking to represent consumers that purchased Softsoap Antibacterial any time since it first launched many years ago, plaintiffs vastly reach beyond the applicable statutes of limitations. (*Infra* § II.)

On these grounds and as discussed below, plaintiffs' Complaint should be dismissed.

Factual Background

Softsoap Antibacterial is one category of dozens of products sold under the Softsoap brand. (*See* Consolidated Amended Class Action Complaint (Dkt. No. 24) ¶ 54 (citing Colgate webpage for Colgate's "Classics" liquid hand soap collection[1]).) Softsoap Antibacterial was a consumer hand soap that contained triclosan, an antibacterial agent. (Compl. ¶¶ 2-3.)

For decades, the U.S. Food & Drug Administration ("FDA") has actively evaluated the

[1] A screenshot of the website is attached as Exhibit 1 to the Affidavit of Arthur Roberts, filed concurrently with this motion.

safety, efficacy, and labeling of triclosan-containing products, such as Softsoap Antibacterial. (Compl. ¶ 4; *see also infra* § I.) The FDA's evaluation of these products is ongoing, and "[i]n 2010, the [FDA] issued a press release advising consumers that it was reviewing both the safety and effectiveness of products containing triclosan." (Compl. ¶ 48.) The "FDA is reviewing all of the available evidence on this ingredient's safety in consumer products." (*Id*. ¶ 74.)

In the midst of the FDA's ongoing evaluation of triclosan, plaintiffs have filed their Complaint. It asserts five state-law claims, each on behalf of a separate subclass. Count I asserts violation of various states' consumer-protection laws.[2] (Compl. ¶¶ 101–14.) Count II asserts a claim for breach of express warranty.[3] (*Id*. ¶¶ 115–23.) Count III asserts a claim for breach of implied warranty.[4] (*Id*. ¶¶ 124–33.) Count IV asserts a claim for unjust enrichment.[5] (*Id*. ¶¶ 134–39.) And finally, Count V seeks injunctive relief.[6] (*Id*. ¶¶ 140–46.)

Each claim shares a similar set of alleged facts. Plaintiffs contend that Colgate's labels and advertising for Softsoap Antibacterial contained the following statements:

- "Antibacterial" (Compl. ¶ 51);

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[2] Plaintiffs assert this claim on behalf of the Consumer Protection States Class, which consists of California, Florida, Illinois, Nevada, and New Jersey residents who bought Softsoap Antibacterial. (Compl. ¶ 87.)

[3] Plaintiffs assert this claim on behalf of the Non-Privity Breach of Express Warranty States Class, which consists of California, Florida, Illinois, Nevada, New Jersey, and South Carolina residents who bought Softsoap Antibacterial. (Compl. ¶ 87.)

[4] Plaintiffs assert this claim on behalf of the Non-Privity Breach of Implied Warranty States Class, which consists of California, Florida, Nevada, New Jersey, and South Carolina residents who bought Softsoap Antibacterial. (Compl. ¶ 87.)

[5] Plaintiffs assert this claim on behalf of the Unjust Enrichment States Class, which consists of Florida, Illinois, Nevada, New Jersey, and South Carolina residents who bought Softsoap Antibacterial. (Compl. ¶ 87.)

[6] Plaintiffs assert this claim on behalf of the Injunctive Relief States Class, which consists of California, Florida, Illinois, Nevada, New Jersey, and South Carolina residents who bought Softsoap Antibacterial. (Compl. ¶ 87.)

- "clinically proven to eliminate 99% of germs your family encounters" (*Id*. ¶¶ 2, 52-54);
- "kills 99% of common germs" (*Id*. ¶ 2);
- "dermatologist tested" (*Id*. ¶¶ 2, 52);
- "offers antibacterial protection" (*Id*. ¶¶ 2, 55-56);
- "Goodbye Germs—Hello World" (*Id*. ¶¶ 2, 56);
- "America's most trusted handsoap" (*Id*. ¶¶ 2, 57).

Based on these alleged marketing statements, and nothing further, plaintiffs contend Colgate has marketed Softsoap Antibacterial as more effective at eliminating germs than washing with ordinary liquid hand soaps. (*See, e.g., id*. ¶¶ 2, 84(a), (e).) They claim this supposed implied comparison is false and that Softsoap Antibacterial is no more effective than regular hand soap. (*See, e.g., id*. ¶ 2.) But plaintiffs do not (and cannot) allege that Colgate ever explicitly compared Softsoap Antibacterial to, or even mentioned, regular hand soap. Moreover, none of the comparative-effectiveness studies plaintiffs cite analyze Softsoap Antibacterial. (*Id*. ¶¶ 36–43, 68-74.)

Plaintiffs further do not allege that any of Colgate's alleged express statements—that Softsoap Antibacterial eliminates 99% of germs, is dermatologist tested, or offers antibacterial protection—are actually false. In fact, plaintiffs admit triclosan *does* kill at least "some types of bacteria" (*id*. ¶ 35) and thus, by definition, is "antibacterial." In place of any allegation that the express claims are false, plaintiffs—citing a number of publicly available sources since 2000 (*id*. ¶¶ 36-43, 68-73)—merely contend Colgate's labeling statements are *unsubstantiated*. In particular, plaintiffs allege that Colgate "has no substantiation for the claims it makes regarding the 'clinically proven' nature of its product or the greater effectiveness of its Product" (*id*. ¶¶ 8, 59, 82) and that the FDA "does not have evidence" or "has not received evidence" to substantiate

the comparative effectiveness of triclosan products. (*Id.* ¶ 3.) Plaintiffs further claim Colgate did not correct consumer misconceptions or disclose the risks of triclosan. (*Id.* ¶¶ 6, 8, 79, 84(b)-(c), (e).) The Complaint does not, however, cite any study that concludes that Colgate's express claims regarding Softsoap Antibacterial are false.

Plaintiffs plead only economic injuries from their alleged purchase and use of Softsoap Antibacterial. (*Id.* ¶¶ 5, 9, 11, 78, 80.) Despite plaintiffs' extensive allegations regarding the purported health risks of triclosan (*id.* ¶¶ 4, 32–34, 39, 49, 50, 74), plaintiffs do not allege any health-related injuries caused by Softsoap Antibacterial.

Argument

I. THE COURT SHOULD DISMISS THE COMPLAINT UNDER THE PRIMARY JURISDICTION DOCTRINE

Plaintiffs admit the FDA is engaging in "an ongoing scientific and regulatory review" of "both the *safety and effectiveness* of products containing triclosan," such as Softsoap Antibacterial. (Compl. ¶¶ 3, 48 (emphasis added).) Nevertheless, instead of waiting for the FDA's guidance—which plaintiffs admit is imminent—plaintiffs ask the Court to make its own determination on the safety and effectiveness of Softsoap Antibacterial. Whether Softsoap Antibacterial is more effective than conventional liquid hand soaps, or whether it poses safety risks Colgate would have to disclose to consumers, or whether Colgate's clinical efficacy testing methods were consistent with FDA standards, are all issues within the purview of the FDA's regulatory duties set by Congress. The claims here all relate to the safety, effectiveness, and labeling of triclosan—issues the FDA is currently evaluating.

A. Standard For The Primary Jurisdiction Doctrine

The primary jurisdiction doctrine governs the "proper relationships between the courts and administrative agencies charged with particular regulatory duties." *United States v. W. Pac.*

R.R. Co., 352 U.S. 59, 63 (1956). In deference to the need for regulatory uniformity and the specialized and superior expertise agencies bring to bear, the doctrine permits dismissal or stays when adjudicating a claim "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Id.* at 63-64; *Comm. of Mass. v. Blackstone Valley Elec. Co.*, 67 F.3d 981, 992 (1st Cir. 1995) (citing "eminently sensible notion" of deferring to agency decisionmaking "in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion"); *Am. Auto. Mfrs. Assoc. v. Mass. Dep't of Env. Prot.*, 163 F.3d 74, 80-81 (1st Cir. 1998) (primary jurisdiction applies where there is need for "uniform answer applicable nationally"); *Pejepscot Indus. Park, Inc. v. Maine Cent. R.R. Co.*, 215 F.3d 195, 205 (1st Cir. 2000) (primary jurisdiction doctrine intended to "serve as a means of coordinating administrative and judicial machinery" and to "promote uniformity and take advantage of agencies' special expertise").

Although there is no "fixed formula" for the primary jurisdiction doctrine, *id.*, three factors guide its application: (1) whether the agency determination lies at the heart of the task assigned the agency by Congress; (2) whether agency expertise is required to unravel intricate, technical facts; and (3) whether, though perhaps not determinative, the agency determination would materially aid the court. *See Blackstone*, 67 F.3d at 992 (citing *Chicago Mercantile Exchange v. Deaktor*, 414 U.S. 113, 114–15 (1973)). Applying this or similar standards, courts frequently defer to the FDA's expertise over product labeling and advertising, even where the courts might be independently capable or competent to decide such issues.[7]

[7] *E.g.*, *Pejepscot*, 215 F.3d at 205-06 (deferring to agency under primary jurisdiction doctrine because agency's determination would "materially aid the district court" and "promote uniformity"); *Gordon v. Dwight*, 2010 WL 1341184, at *1-*2 (N.D. Cal. April 2, 2010) (because

B. The FDA's Determinations On The Safety, Efficacy And Labeling Of Triclosan Products Lie At The Heart Of Its Tasks Assigned By Congress

Congress specifically tasked the FDA to "promote the public health by promptly and efficiently *reviewing clinical research* and taking appropriate action on the *marketing of regulated products* in a timely manner" and "with respect to such products, protect the public health by ensuring that . . . human and veterinary drugs are *safe and effective*." 21 U.S.C. § 393(b)(1), (2)(B) (emphasis added). To implement these congressional duties, the FDA publishes the conditions under which categories of drugs are "safe and effective and not misbranded" in its regulations, known as "monographs."[8] 21 C.F.R. § 330.10. Triclosan—an over-the-counter ("OTC") drug—is one of the antimicrobial drugs that the FDA regulates through this process. (Compl. ¶ 4 (admitting that FDA's "regulated products" includes triclosan hand soaps).)

FDA regulated product labeling for 30 years, and was still considering public comments and other issues related to plaintiff's claims, it "would be inappropriate for this court to assume the FDA's regulatory role, and to interpret scientific studies or other evidence to determine whether the labeling . . . should be changed"); *Chavez v. Nestle USA, Inc. et al.*, No. 09-cv-09192 (C.D. Cal. Jan. 10, 2011), *adopted in* 2011 WL 2150128 (C.D. Cal. May 19, 2011) (concluding false-advertising claims subject to dismissal under primary jurisdiction doctrine and stating "there is still a question whether the courtroom is the appropriate forum for resolving scientific disputes regarding the efficacy of [ingredients in defendant's products]"); *Mut. Pharm. Co. v. Watson Pharm., Inc.*, 2009 WL 3401117, at *5 (C.D. Cal. Oct. 19, 2009) (denying plaintiff's motion for preliminary injunction due to weakness of plaintiff's false-advertising contentions concerning product labels; "disputes concerning the content of [the product's] labels and inserts falls even more squarely within the primary jurisdiction of the FDA"); *American Home Prod. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145-46 (S.D.N.Y. 1987) (dismissing antitrust claims because public interest is best served by leaving OTC drug labeling regulation and enforcement to "expert" regulatory function of FDA); *Israel v. Baxter Labs., Inc.*, 466 F.2d 272, 280-81 (D.C. Cir. 1972) (holding that even though plaintiffs' claims were cognizable in the courts, enforcement of their claims involved "a determination of the safety and efficacy of [drug] . . . a function clearly within the 'specific competence' of the FDA" in view of the "comprehensive scheme enacted by Congress" in determining the efficacy and safety of drugs).

[8] Monographs prescribe "drug composition, labeling, and manufacturing controls" for over-the-counter drugs. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 650 (1973).

Consistent with its Congressional assignment, the FDA has taken extensive measures to evaluate OTC drugs including triclosan. The FDA first employed "advisory review panels of qualified experts" with the expertise to "evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise [the Commissioner of Food and Drugs] on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(1). After the advisory review panel conducted more than two dozen working meetings over the course of nearly two years and drafted its findings, the FDA reviewed the panel's recommendations and then further solicited public comment regarding its proposed rules for topical antimicrobial drug products for over-the-counter use, including antibacterial hand soaps containing triclosan. *See* Proposal To Establish a Monograph for OTC Topical Antimicrobial Products, 39 Fed. Reg. 33103 (Sept. 13, 1974). A few years later, in 1978, the FDA issued a Tentative Final Monograph governing these products. 43 Fed. Reg. 1210 (Jan. 6, 1978) (to be codified at 21 C.F.R. pt. 333). The 1978 Tentative Final Monograph established guidelines for the labeling (*id.* at 1212-14, 1233), safety and effectiveness (*id.* at 1223, 1230-33), and testing guidelines for the study of triclosan-containing hand soaps (*id.* at 1240-53), among other things.

In a second Tentative Final Monograph in 1994, as part of its "ongoing review of OTC drug products," the FDA proposed revised guidelines for the appropriate labeling of professional or consumer antiseptic handwashes. *See* 59 Fed. Reg. 31402 (June 17, 1994) (to be codified at 21 C.F.R. pts. 333, 369). The FDA provided guidelines on the safety and effectiveness of triclosan, and noted that its "antimicrobial rulemaking is broad in scope, encompassing products that may contain the same active ingredients [such as triclosan] but are labeled and marketed for

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Manufacturers of consumer products containing triclosan would need to comply with the

different intended uses." *Id.* at 31427-28, 31403. The 1994 Tentative Final Monograph stated the FDA would modify its proposed testing guidelines, and that antimicrobial formulations would have to meet those guidelines to prove clinical effectiveness. *Id.* at 31430-33. In May 2003, the FDA reopened the administrative record to accept additional comments for the "final classification of [the ingredients considered in the Tentative Final Monograph, including triclosan] and the testing criteria to be established in the Final Monograph." 68 Fed. Reg. 32003.

In February 2010, the FDA reported it was still "working to issue a proposed rule" to amend the 1994 Tentative Final Monograph, and in developing that rule, will seek, among other things, additional data regarding the safety and effectiveness of topical antimicrobial products for consumer use" including "consumer antibacterial soaps and washes." (Exhibit 2 to Roberts Aff., at 1.) In no uncertain terms, the FDA stated: "Antibacterial soaps and washes continue to be subject to regulation under the topical antimicrobial drug products monograph." (*Id.* at 2.) Two months later, the FDA announced it was further evaluating the most recent studies regarding triclosan and would issue its findings in the winter of 2012. (Compl. ¶ 74.) To date, the FDA has not completed its review.[9] (*Id.*)

C. The FDA Has The Specialized Expertise Required To Assess The Intricate Issues Relating To Triclosan

1. The FDA Has Four Decades of Experience Regulating Triclosan

The FDA's *40 years* of experience regulating triclosan provide it with specialized technical expertise, which further weighs in favor of applying primary jurisdiction. *Blackstone*, 67 F.3d at 992 (citing *Deaktor,* 414 U.S. at 114–15). To draft its proposed rules, the FDA

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monograph. 21 C.F.R. § 330.10(b).

[9] Contrary to plaintiffs' allegations, the FDA has not concluded triclosan in antibacterial soaps and body washes provides no benefit over regular soap and water. (*E.g.* Compl. ¶¶ 3, 73.)

enlisted an advisory panel of qualified experts, who reviewed, analyzed, and evaluated the research data to formulate recommendations. But the process did not stop there; the FDA further solicited comments from the public and the industry to issue its tentative rules governing use of triclosan. As the FDA's Director of OTC Drug Products described:

> FDA often receives extensive, voluminous, and conflicting comments and new data and information after publishing a [Tentative Final Monograph]. . . Before a final monograph issues . . . FDA expends significant resources to review and evaluate all comments, data, and information submitted after publication of the TFM, as described above, together with the entire record. For certain monographs, like the monograph for topical antimicrobial drug products, the comments, data, and information often relate to complex scientific, medical, policy, and legal issues. When all such issues have been resolved by the appropriately trained FDA employees, [the FDA's Division of Nonprescription Regulation Development] prepares a draft document that analyzes the issues, responds to public comments raised, and drafts the final monograph for the relevant class of OTC drugs. The draft is then routed to various components within FDA for scientific and medical review, consistency of policy, and legal sufficiency.

(Declaration of Charles J. Ganley, M.D. ("Ganley Decl."), *NRDC v. U.S.F.D.A.*, Case No. 10-cv-05690 (S.D.N.Y.) (Dkt. No. 17) ¶¶ 15-16 (attached as Exhibit 3 to the Roberts Aff.))

Resolving the safety, effectiveness and proper labeling and marketing of Softsoap Antibacterial will involve analyzing clinical trials and recent research on triclosan, and "requires the resolution of large numbers of complex medical, scientific, policy, and legal issues in such areas as ingredient classification, drug testing and formulation, and drug labeling, among others." (*Id.* ¶ 24.) These are precisely the types of issues the FDA is "better equipped [to resolve] than courts by specialization, by insight gained through experience, and by more flexible procedure." *Writers Guild of America, W., Inc. v. American Broadcasting Co., Inc.*, 609 F.2d 355, 363 (9th Cir. 1979) (quoting *Far E. Conf. v. United States*, 342 U.S. 570, 575 (1952)) (holding Federal

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Instead, the FDA has made clear its investigation is ongoing, and will issue rules regarding the safety, effectiveness and marketing of antimicrobial products.

Communications Commission (FCC) had primary jurisdiction over claim regarding FCC's family-viewing policy); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508-09 (7th Cir. 2009) (holding that "[t]he FDA should be given a chance to opine on the proper labeling before a Lanham Act suit is filed . . . since it has more experience with consumers' understanding of drug labels than judges do"); *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645, at *2-3 (S.D.N.Y. Nov. 22, 2000) (dismissing case pursuant to primary jurisdiction doctrine because FDA "has the relevant expertise" to decide drug labeling issues). "[T]he FDA alone can balance the potentially competing concerns of safety and effectiveness" and thus "common law and state law liability that is also premised on a product's safety and effectiveness can only upset that balance." *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008).

Dismissal under the primary jurisdiction doctrine is particularly appropriate when the case involves an ongoing public health issue. *Gordon v. Church & Dwight Co.*, No. C 09-5585, 2010 WL 1341184, at *1–*2 (N.D. Cal. Apr. 2, 2010). In *Gordon*, the complaint sought to include an additional warning on latex condoms about sexually transmitted disease. *Id.* at *2. The court dismissed pursuant to the primary jurisdiction doctrine because the FDA was "still considering public comments and other data in connection with warnings similar to those that plaintiffs seek to have the court impose. Thus, this issue remains under review." *Id.* As the *Gordon* court explained, it would be "inappropriate . . . to assume the FDA's regulatory role," especially where the issue raised "continues to be a significant threat to public health." *Id.*

Here, plaintiffs similarly contend Colgate should not have labeled its triclosan-containing liquid hand soap as "antibacterial," and that triclosan is a "human health risk" and "an environmental risk" by allegedly "alter[ing] hormone regulation in animals," and contributing to

"making bacteria resistant to antibiotics." (Compl. ¶¶ 3, 4, 32-35.) Although plaintiffs may argue the parties can retain experts to interpret scientific and clinical data on triclosan to advise the Court on the safety and efficacy of triclosan, such experts cannot supplant the extensive resources and expertise of the FDA. The scientific merits of these issues should first be decided by FDA experts who, pursuant to their statutory authority, are trained to analyze the latest scientific evidence and account for public comments from all interested parties. The action here, limited by the rules of evidence and federal procedure, is not the best forum to regulate nationwide liability for issues Congress has delegated to the FDA.

2. Deferring To The FDA Would Promote Uniformity In The Regulation Of Triclosan And Other Drugs

Plaintiffs' Complaint further raises issues that require uniformity in administration. The judgment here could potentially conflict with other rules or regulations regarding the safety and efficacy of OTC drugs promulgated by the FDA, and with numerous other courts being called on to resolve the same issues. *See Computer Sciences Corp. v. N.L.R.B.*, 677 F.2d 804, 808 (11th Cir. 1982) (applying primary jurisdiction doctrine in part because of "interest in uniformity"); *Spencer v. Puerto Rico Marine Mgmnt., Inc.*, 644 F. Supp. 172, 178 (M.D. Fla. 1986) (invoking primary jurisdiction doctrine because of agency's "expertise" and "to avoid inconsistent adjudication"). Thus, even though the Court *could* resolve the factual questions raised by this lawsuit, it would not be able to "provide the uniformity of resolution required by the regulatory scheme." *Locust Cartage Co., Inc. v. Trans. Freight Lines, Inc.*, 430 F.2d 334, 340 (1st Cir. 1970). The FDA is responsible to ensure its rules apply uniformly and are not internally inconsistent. "Before issuing a final monograph, FDA must be certain that it is consistent with existing regulations involving other drugs and products regulated by FDA. The monographs must also be consistent with each other in areas such as combinations of, and appropriate doses

of, OTC drugs covered by more than one monograph, and they must be consistent with FDA's treatment of prescription drugs." (Ganley Decl. ¶ 17.)

Inconsistent and contradictory judicial rulings regarding labeling and marketing language could lead to consumer confusion. They could also create differing and irreconcilable obligations imposed on the same company. For example, some courts could find Colgate is obligated to label liquid hand soap containing triclosan as "antibacterial," while others could forbid it. Or courts could find that the "antibacterial" claim is misleading while the FDA expressly requires that Colgate and other manufacturers label triclosan products with the "antibacterial" label. Or the courts could reach conclusions that conflict with the FDA's forthcoming or existing regulations on triclosan and OTC drugs.

In addition, differing rulings could inadvertently bestow a competitive advantage or handicap on one company over another regarding use of the same ingredient and identical claims. These are all results that courts applying the primary jurisdiction doctrine have sought to avoid. *See Computer Sciences Corp.*, 677 F.2d at 808 (applying primary jurisdiction doctrine in part because the court's decision "might reflect judgments differing from those of the agency with expertise"); *All One God Faith, Inc. v. Hain Celestial Gr., Inc.*, 2010 WL 2133209, at *6–7 (N.D. Cal. May 24, 2010) (USDA had primary jurisdiction over claim regarding product labeling because it "would be inappropriate for this Court to adjudicate Plaintiff's . . . claim and impose a potentially conflicting set of standards"); *Friends of Santa Fe City v. LAC Minerals, Inc.*, 892 F. Supp. 1333, 1350 (D.N.M. 1995) (New Mexico state agency had primary jurisdiction in part because "Defendants could be subjected to conflicting orders of both the Court and the administrative agency").

The opinion in *Heller v. Coca-Cola Co.* 646 N.Y.S.2d 524 (N.Y. App. Div. 1996) is instructive. The plaintiffs in *Heller* claimed that Aspartame, an ingredient in Coca-Cola, caused the soda to become spoiled. *Id.* at 525. The complaint asserted claims similar to those here: "fraud and deceit, consumer fraud, and unjust enrichment." *Id.* The Appellate Division affirmed dismissal under the primary jurisdiction doctrine because Aspartame was regulated by the FDA. The FDA had explicitly permitted use of Aspartame in soda and had "promulgated labeling requirements regarding" its use. *Id.* at 526. The Appellate Division said its holding would "ensure that there will be national uniformity in the labeling of Aspartame and will utilize the special expertise of the FDA in evaluating the relevant factors for approving food additives." *Id.*

The *Heller* court's concerns about uniformity and the FDA's expertise in labeling are equally applicable here. Accordingly, the case should be dismissed in light of the FDA's jurisdiction over and pending regulation of the same issues.

D. The FDA's Determination Would Materially Aid The Court

The FDA's decision on safety, efficacy and labeling requirements for triclosan and other antibacterial agents will significantly aid this Court in determining how liability and damages should be assessed. Indeed, the FDA has provided clear indication in its tentative rulemaking that the final monograph will address the very questions plaintiffs ask this Court to resolve:

- **Are triclosan hand soaps such as Softsoap Antibacterial <u>more effective</u> than conventional soap and water?** (*E.g.* Compl. ¶¶ 2, 5, 84(a).)

  > *See* Tentative Final Monograph, 43 Fed. Reg. 1210 ("This tentative final monograph would establish conditions for the safety, **<u>effectiveness</u>**, and labeling of over-the-counter (OTC) products such as antibacterial soaps . . . in accordance with procedures for the agency's ongoing review of OTC drug products") (emphasis added), 1240 (for safety and **<u>effectiveness</u>**, "[t]he following tests should be performed for all product classes …"), 1241-42 (discussing FDA's intent to "modify the testing guideline" and describing guidelines that "will characterize the **<u>effectiveness</u>** of an antimicrobial ingredient" as well as other "specific protocols to prove safety and **<u>effectiveness</u>**") (emphasis added).

- **Are triclosan hand soaps such as Softsoap Antibacterial unsafe such that manufacturers should inform consumers of the risks?** (*E.g.* Compl. ¶¶ 8, 84(b), (c).)

  See Tentative Final Monograph, 43 Fed. Reg. 1210 ("This tentative final monograph would establish conditions for the **safety**, effectiveness, and labeling of over-the-counter (OTC) products such as antibacterial soaps . . . in accordance with procedures for the agency's ongoing review of OTC drug products") (emphasis added), 1213 ("it is the conclusion of the Commissioner that the limited consumer use of antimicrobial-containing products under normal conditions in the population at large **does not constitute a risk** that would warrant [a caution against overuse] label warning or removal of such products from the OTC marketplace"), 1240 (for safety and effectiveness, "[t]he following tests should be performed for all product classes …"), 1241-42 (discussing FDA's intent to "modify the testing guideline" and describing guidelines that "will characterize the effectiveness of an antimicrobial ingredient" as well as other "specific protocols to prove **safety** and effectiveness") (emphasis added); Amended Tentative Final Monograph, 59 Fed. Reg. 31402, 31426-27 (discussing "chronic exposure" tests to assess "**safety of the long-term use of triclosan**") (emphasis added).

- **Do triclosan hand soaps create the risk of antibiotic resistance or alter hormone regulation with long-term use?** (*E.g.* Compl. ¶ 4.)

  See Tentative Final Monograph, 43 Fed. Reg. 1210. 1213 ("it is the conclusion of the Commissioner that the limited consumer use of antimicrobial-containing products under normal conditions in the population at large **does not constitute a risk** that would warrant [a caution against overuse] label warning or removal of such products from the OTC marketplace"); Amended Tentative Final Monograph, 59 Fed. Reg. 31402, 31426-27 (discussing "**chronic exposure**" tests to determine **safety of long-term use of triclosan**) (emphasis added).

- **Do available clinical and/or scientific data support the conclusion that triclosan hand soaps such as Softsoap Antibacterial are safe and/or more effective than conventional soap and water?** (*E.g.* Compl. ¶¶ 3, 4, 84(f).)

  See Tentative Final Monograph, 43 Fed. Reg. 1210, 1231 ("adequate **safety and effectiveness data are not yet available** to permit final classification . . . From the data submitted the Commissioner concludes that there is no known hazard to the general public from the use of triclosan in concentrations not greater than 1 percent.") (emphasis added); FDA Consumer Health Information, *Triclosan: What Consumers Should Know* (discussed in Compl. ¶¶ 48, 73) ("FDA is working to incorporate the most up-to-date data and information into the regulations that govern the use of triclosan in consumer products") (attached as Exhibit 4 to Roberts Aff.).

- **Is such clinical and/or scientific test data competent or reliable?** (*E.g.* Compl. ¶ 7.)

  See Tentative Final Monograph, 43 Fed. Reg. 1210, 1240 (for safety and effectiveness, "[t]he following tests should be performed for all product classes …"), 1241-42 (discussing FDA's intent to "**modify the testing guideline**" and describing guidelines that "will characterize the effectiveness of an antimicrobial ingredient" as well as other "**specific protocols** to prove safety and effectiveness") (emphasis added).

- **How should triclosan hand soaps such as Softsoap Antibacterial be labeled and marketed?** (*E.g.* Compl. ¶ 2, 5, 6, 9, 10, 11.)

  See Tentative Final Monograph, 43 Fed. Reg. 1210 ("This tentative final monograph would establish conditions for the safety, effectiveness, and **labeling** of over-the-counter (OTC) products such as antibacterial soaps . . . in accordance with procedures for the agency's ongoing review of OTC drug products") (emphasis added), 1213 ("it is the conclusion of the Commissioner that the limited consumer use of antimicrobial-containing products under normal conditions in the population at large **does not constitute a risk that would warrant [a caution against overuse] label warning** or removal of such products from the OTC marketplace") (emphasis added).

The Court therefore would greatly benefit from the results of the FDA's monograph on consumer antibacterial handsoap products in determining whether Colgate should be liable for its sale and marketing of Softsoap Antibacterial.

II. THE COURT SHOULD DISMISS CLAIMS BASED ON PURCHASES MADE OUTSIDE THE APPLICABLE STATUTES OF LIMITATIONS

On its face, the Complaint seeks to certify an unprecedented broad class of consumers: all persons who reside in the relevant states (*see supra* fns. 2, 3, 4, 5, 6) and who purchased Softsoap Antibacterial "any time *from the date of its commercial launch* through the final disposition of this and any and all related actions." (Compl. ¶ 87 (emphasis added).) In other words, plaintiffs would like this Court to ignore every statute of limitation that applies to their claims and force Colgate to extract information from the faded memories of current, former and deceased employees and search for 20-year old evidence (that in all likelihood no longer exists)

in order to defend itself against plaintiffs' claims for *every single purchase* of Softsoap Antibacterial ever made in the six states involved in this case.

Plaintiffs' sole justification for this broad-sweeping class is three meager paragraphs (Compl. ¶¶ 98-100), where they allege Colgate engaged in acts of "fraudulent concealment" and that plaintiffs had "no reasonable way to discover" the truth about triclosan. In the same breath, plaintiffs allege there were multiple examples of *publicly available* documents that put them on notice of their potential claims "as early as 2000"—well after the commercial launch of Softsoap Antibacterial.[10] Thus, to the extent plaintiffs reach for the sky with their claims against all Softsoap Antibacterial products ever sold, such claims should be dismissed in accordance with the statutes of limitation.[11] *See, e.g., Santana-Castro v. Toledo-Davila*, 579 F.3d 109, 113–14 (1st Cir. 2009) (affirming dismissal of complaint based on statute of limitations because facts establishing defense were "clear 'on the face of the plaintiff's pleadings'").

A. The Discovery Rule Does Not Extend The Statutes Of Limitation

With the exception of South Carolina, the governing statutes explicitly state that plaintiffs' warranty claims accrue on the day the goods were *purchased*, not when the claims were discovered. *See* Cal. Comm. Code § 2725(2); Fla. Stat. Ann. §§ 95.031(1), 95.11(3)(k), (p);[12] 810 Ill. Comp. Stat. 5/2-725(2); Nev. Rev. Stat. § 104.2725(2); N.J. Stat. Ann. § 12A:2-

[10] Although plaintiffs do not allege the date of the commercial launch of Softsoap Antibacterial, that is of no moment. Plaintiffs are, as a matter of law, restricted by the applicable statutes of limitations.

[11] The statutes of limitation that govern plaintiffs' substantive claims are set forth in Appendix A to this Motion. The limitation periods range from three to six years, with most set at four years. Appendix A lists the date of the last actionable purchase of Softsoap Antibacterial that can be included in the class period.

[12] Although the Florida statute does not state that the discovery rule does not apply, the Florida Supreme Court has held that unless a provision in the statute of limitations expressly states that the discovery rule applies, then the discovery rule does not apply. *See Fed. Ins. Co. v.*

725(2). These warranty claims therefore accrued on the day of the purchase and the discovery rule cannot apply to toll these claims.

For at least some of the remaining claims, Colgate expects plaintiffs to argue that the discovery rule delays accrual of claims until a plaintiff discovered or should have discovered the facts underlying his claims. *See generally*, *Conrad v. Hazen*, 140 N.H. 249, 250–51 (1995) (explaining discovery rule). Even assuming the discovery rule could apply, plaintiffs should have learned of their claims well before they filed suit. For example, plaintiffs allege several facts that would have put a reasonably diligent plaintiff on notice of his or her claims:

- In 2000, the American Medical Association allegedly stated at its Annual Meeting that "there was no evidence to support a claim that triclosan was an effective antimicrobial agent." (Compl. ¶ 36.)
- In 2000, the Center for Disease Control ("CDC") presented a study that allegedly "proved that triclosan was not demonstrably useful" in hand soap. (*Id.* ¶ 37.)
- In 2002, a study by the National Institutes of Health allegedly stated that "[a]ntibacterial soaps are no better at killing germs than regular soap." (*Id.* ¶ 38.)
- In October 2005, the FDA's Non-Prescription Drug Advisory Committee allegedly concluded "that there was a lack of evidence supporting the benefit" of consumer antimicrobial hand soaps. (*Id.* ¶ 40.) The CDC allegedly confirmed this finding. (*Id.* ¶ 41.).
- In 2007, the University of Michigan, Columbia University, and Tufts University scientists allegedly "determined that soaps containing triclosan in liquid soap do not show a benefit above" regular soap. (*Id.* ¶ 42.)

Although not cited in the Complaint, studies with similar conclusions have been in the news all across the country since the early 2000's and before:[13]

Sw. Fla. Ret. Ctr., Inc., 707 So.2d 1119, 1122 (Fla. 1998); *Beck v. Lazard Freres & Co., LLC*, 175 F.3d 913, 914 (11th Cir. 1999).

[13] As set forth in the accompanying Request for Judicial Notice, newspaper articles are the proper subject of judicial notice. *Nw. Bypass Gr. V. United States Army Corps of Eng'rs*, 488 F. Supp. 2d 22, 25–26 (D.N.H. 2007) (stating "depending on the content, facts reported in newspaper articles may be considered 'generally known'").

- Judith Wakefield, *Washing Hands With Soap, Water Vital to Good Health*, Press Journal (Vero Beach, FL), Apr. 19, 1998 (stating soaps with triclosan have "essentially the same [result] as with regular soap) (attached as Exhibit 5 to Roberts Aff.);

- Anita Srikameswaran, *Seeing Clean in a Whole New Light; the Craze Over Antibacterial Soaps Washes Away the Fact That Simple Soap and Water Work Just Fine*, Pittsburgh Post-Gazette (Pennsylvania), Nov. 5, 2002 (discussing study showing antibacterial hand soaps were no more effective than regular soap) (attached as Exhibit 6 to Roberts Aff.);

- Howard Markel, *Germ Warfare*, N.Y. Times, Sept. 6, 2003 (stating antibacterial hand soaps "do little good" and noting study showing that antibacterial soaps have shown no effect on incidence of common infections in home) (attached as Exhibit 7 to Roberts Aff.);

- John O'Neil, *Got Germs? Regular soap Will Do*, N.Y. Times, Mar. 2, 2004 (stating "using antibacterial soaps at home does not add any more protection for healthy people against infections, researchers reported yesterday") (attached as Exhibit 8 to Roberts Aff.);

- Zerah Lurie, *Super Soap—It's a Wash for Most of Us*, Orlando Sentinel, Aug. 17, 2004 (stating there is "little actual science showing that the average consumer will benefit from antibacterial" products, including triclosan-containing hand soap) (attached as Exhibit 9 to Roberts Aff.);

- Rita Rubin, *Antiseptic Soaps Bubble Up Again*, USA Today, Oct. 20, 2005 (stating scientists "cite a lack of evidence that [anti-bacterial soaps] are any more effective . . . than plain soap and water") (attached as Exhibit 10 to Roberts Aff.).

Although Colgate disagrees with the opinions set forth in these articles, they demonstrate that the issue of the comparative effectiveness of triclosan-containing hand soap has been debated publicly for many, many years. And these publications, studies, and news articles, sufficed to put plaintiffs on notice of their claims. *See In re Traysol Prods. Liability Litig.*, No. 08-MD-1928, 2010 WL 6098571, at *12 (S.D. Fla. Mar. 16, 2010) (holding discovery rule did not save plaintiffs' claim because scientific article discussing underlying facts put plaintiffs on notice of claims); *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 403 (3d Cir. 2006) (holding that media accounts of funds' connections to bankrupt company put plaintiff investors on notice of claims). Thus, even assuming the discovery rule

could apply to some of plaintiffs' claims, those claims would have accrued in the early 2000s and would therefore still be untimely.[14]

B. Neither Equitable Tolling Nor Fraudulent Concealment Toll The Statutes Of Limitation

Plaintiffs also attempt to circumvent the statutes of limitation by alleging Colgate "intentionally concealed" that "Softsoap Antibacterial was no more effective than washing with regular soap and water." (Compl. ¶¶ 98–100.) As will be explained below, Colgate never made the representation that Softsoap Antibacterial was more effective than washing with regular soap or water, nor did Colgate conceal facts, either intentionally or inadvertently, regarding the efficacy of Softsoap Antibacterial. Merits aside, however, according to plaintiffs, this bare allegation is somehow sufficient to toll the statute of limitations. *See id.* Not so.

First, with the exception of South Carolina, each of Plaintiffs' warranty claims accrue upon delivery of the allegedly non-conforming product, "regardless of the aggrieved party's lack of knowledge of the breach."[15] Second, even if equitable tolling *could* apply to any of Plaintiffs' remaining claims, Plaintiffs have failed to show that it does. In the states at issue in this case, equitable tolling generally requires some active concealment of the operative facts, or some "extraordinary" circumstances that prevent a plaintiff from filing suit. *See Sagehorn v. Engle*, 141 Cal. App. 4th 452 (Cal. Ct. App. 2006); *Pro Tech Monitoring, Inc. v. State, Dep't of Corrections*, 72 So.3d 277, 280 (Fla. Dist. Ct. App. 2011); *IPF Recovery Co. v. Ill. Ins. Guar. Fund*, 356 Ill. App. 3d 658,663 (Ill. App. Ct. 2005); *Freeman v. State*, 788 A.2d 867, 880 (N.J.

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[14] Even if the Court decides not to take judicial notice of the additional articles not cited in the Complaint, the studies and reports cited in the Complaint were sufficient to put plaintiffs on notice of their claims. *See, e.g., Traysol*, 2010 WL 6098571, at *12.

[15] Cal. Com. Code § 2725(2); Fla. Stat. Ann. § 95.11(3)(f), (k), (p); *Fed. Ins. Co. v. Sw. Fla. Ret. Ctr., Inc.*, 707 So.2d 1119, 1122 (Fla. 1998) (holding that unless statute explicitly states

Sup. Ct. App. Div. 2002); *Pelzer v. State*, 662 S.E.2d 618, 620 (S.C. Ct. App. 2008). *Cf. Copeland v. Desert Inn Hotel*, 673 P.2d 490, 492 (Nev. 1983) (stating misleading or deceptive statements are among factors to consider). Plaintiffs, however, have alleged no *facts* that even come close to making the required showing. They merely allege in a conclusory way that Colgate "intentionally concealed" facts from plaintiffs. But the First Circuit has made clear that conclusory allegations cannot sustain a claim of equitable tolling: "conclusory assertions rarely will suffice to meet [the plaintiff's] burden" of establishing equitable tolling. *Trenkler v. United States*, 268 F.3d 16, 25 (1st Cir. 2001) (affirming denial of equitable tolling).[16]

If Plaintiffs' allegations were enough to invoke equitable tolling, then any plaintiff, in any case, could simply assert fraudulent concealment, without any supporting facts, and defeat a statute-of-limitations argument. That is not the law, *see id.*, and plaintiffs cannot sue over *every purchase of Softsoap Antibacterial ever made*. Their claims outside the applicable statutes of limitation should be dismissed.

III. PLAINTIFFS FAIL TO STATE A CLAIM

To survive a motion to dismiss, a complaint must contain sufficient factual matter to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009); *see also Katz v. Pershing, LLC*, 672 F.3d 64, 72 (1st Cir. 2012). In other words, the complaint "must include 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Katz*, 672 F.3d at 73 (quoting *Iqbal*,

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discovery rule applies, it does not); 810 Ill. Comp. Stat. 5 / 2-725(2); Nev. Rev. Stat. § 104.2725(2); N.J. Stat. Ann. § 12A:2-725(2).

[16] Plaintiffs' citations to multiple studies and publications that allegedly show the very facts upon which plaintiffs base their claims—namely that antibacterial hand soap is no more effective than regular soap—undermines their conclusory claim that "they had no reasonable way to discover or detect Colgate's misrepresentations." (*See* Compl. ¶¶ 36–43, 68-74.) This

129 S.Ct. at 1949). Mere conclusory statements "are not entitled to the assumption of truth." *Iqbal*, 129 S. Ct. at 1950; *see also Katz*, 672 F.3d at 73.

A. The Allegedly Implied Superiority Statement Is Not Actionable Under Any Of Plaintiffs' Theories

At the heart of plaintiffs' Complaint is the *implied* comparative claim that Softsoap Antibacterial was superior to ordinary soap. Plaintiffs allege that:

> Colgate's advertising and marketing campaign sends the unmistakably clear, but unconscionably deceptive and unfair message, **that Softsoap Antibacterial is more effective at eliminating germs, protecting the consumer from germs, and thus preventing illness and promoting good health, than washing with ordinary liquid hand soaps that do not carry the risks associated with triclosan.**

(Compl. ¶ 61 (emphasis added).) In every single paragraph of plaintiffs' description of the "Nature of the Action," and repeatedly throughout their Complaint, plaintiffs make clear that they take issue with this *implied* claim of superior effectiveness compared to conventional soaps. (*See id.* ¶¶ 2-12, 26, 51, 52, 53, 58, 62, 63, 64, 78.) However, plaintiffs do not allege any facts showing Colgate ever *expressly* stated on its label or in its advertising or marketing that Softsoap Antibacterial was better or more effective than conventional soap and water.

1. Plaintiffs' Breach Of Express Warranty Claim Based On Colgate's Alleged Implied Representation Must Fail

A claim for breach of express warranty requires a plaintiff to allege an *express* warranty.[17] By definition, "express warranties must be explicit"; an *implicit* statement cannot be the basis of an *express* warranty. *See Sidco Prods. Marketing, Inc. v. Gulf Oil Corp.*, 858 F.2d

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further undermines their claim that Colgate somehow prevented them from discovering the operative facts.

[17] *See, e.g., Nichols v. Wm. Wrigley Jr. Co.*, 2011 WL 181458, at *4 (S.D. Fla. Jan. 19, 2011) (citing *Dunham-Bush, Inc. v. Thermo-Air Serv., Inc.*, 351 So. 2d 351, 353 (Fla. Dist. Ct. App. 1977)); *Hasek v. DaimlerChrysler Corp.*, 745 N.E.2d 627, 634 (Ill. Ct. App. 2001); *In re*

1095, 1098 (5th Cir. 1988) (alleged omission cannot support express-warranty claim).[18] Thus, plaintiffs' claim for breach of warranty fails as a matter of law to the extent it is based on the purported affirmation that Softsoap Antibacterial is superior to regular soap—a statement Colgate never expressly made.

Even if an implied statement was sufficient to plead breach of an express warranty—which it is not—the breach of warranty claim fails for lack of privity. "To recover for the breach of a warranty either express or implied, the plaintiff must be in privity of contract with the defendant." *Weiss v. Johansen*, 898 So. 2d 1009, 1012 (Fla. Dist. Ct. App. 2005); *see also, e.g.*, *Intergraph Corp v. Stearman*, 555 So. 2d 1282, 1283 (Fla. Dist. Ct. App. 1990) (stating that "[p]rivity is required in order to recover damages from the seller of a product for breach of express or implied warranties"); *T.W.M. v. American Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) ("The law of Florida is that to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant. . . "[a] plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant").

Ford Motor Co. E-350 Van Products Liability Litigation (No. II), 2010 WL 2813788, at *8 (D.N.J. July 9, 2010); *Maneely v. General Motors Corp*., 108 F.3d 1176, 1181 (9th Cir. 1997).

[18] *See also Cambridge Engineering, Inc. v. Robertshaw Controls Co.*, 966 F. Supp. 1509, 1524 (E.D. Mo. 1997) (dismissing express-warranty claim "because express warranties must be explicit"); *S.I. Prop. Owners' Ass'n, Inc. v. Pabst Corp.*, 714 S.W.2d 358, 361 (Tex. Ct. App. 1986) (no express warranty created because no evidence of explicit statements, and stating "[a]bove all, however, an express warranty must be explicit"); *Connor v. Bogrett*, 596 P.2d 683, 688 (Wy. 1979) (no express warranty created because "an express warranty of future performance of the goods must be explicit"); *Herbstman v. Eastman Kodak Co.*, 342 A.2d 181, 187 (N.J. 1975) (express warranty did not extend to implied warranty of merchantability, and stating an express warranty "of future condition or performance must be explicit"); Fla. Stat. Ann. § 672.313 (requiring "affirmation of fact or promise made by the seller to the buyer" or "description of the goods" in order to create express warranty); 810 Ill. Comp. Stat. 5/2-313 (same).

Plaintiffs fail to allege that they purchased Softsoap Antibacterial from a Colgate store, and they further do not allege that any class member bought the product directly from Colgate (*see* Compl. ¶¶ 17-25). Nor can they, because Colgate never sold the product directly to them or any purported class member. Nor do they allege that they are eligible for any exceptions to the privity rule, under Florida law or as required under any of the laws of the relevant states. They thus fail to allege any plausible basis for privity, and their warranty claims must fail. *See Point Blank Solutions, Inc. v. Toyobo America, Inc.*, 2011 WL 1833366, at *4-5 (S.D. Fla. May 13, 2011) (dismissing express-warranty claim against product manufacturer because plaintiff did not purchase product directly from manufacturer and therefore lacked privity).

2. Plaintiff Does Not Establish How The Purported Implied Statement Supports The State Consumer Protection or Warranty Claims

Plaintiffs' claims under state consumer protection laws and express warranty claims also cannot be founded on Colgate's alleged implied statements. "An act is deceptive or unfair where it is 'likely to deceive a consumer acting *reasonably* under the same circumstances.'" *Feheley v. LAI Games Sales, Inc.*, 2009 WL 2474061, at *5 (S.D. Fla. Aug. 11, 2009) (emphasis added); *see also, e.g. Janda v. T-Mobile USA*, Inc., 378 Fed. Appx. 705, 707, 709 (9th Cir. 2010) (applying California unfair competition law). Plaintiffs do not plausibly allege any deceptive act or unfair practice that would have reasonably caused plaintiffs any damages, and therefore their claims must fail as a matter of law.

First, the allegedly implied claim that Softsoap Antibacterial is better or is more effective than conventional soap is a non-specific, immeasurable claim that constitutes non-actionable "puffery." Puffing is "an expression of opinion by seller not made as a representation of fact." *N.J. Citizen Action v. Schering-Plough Corp.*, 2002 WL 32344594, at *3 (N.J. Super. Ct. May 12, 2002), *aff'd*, 842 A.2d 174 (N.J. App. Div. 2003). If a statement does not contain any

statements of fact, then the truth or falsity of the statement is moot. *Id.* Statements of puffery often contain "meaningless superlatives that no reasonable person would take seriously." *Barbara's Sales, Inc. v. Intel Corp.*, 879 N.E.2d 910, 926 (Ill. 2007); *Tylka v. Gerber Prods. Co.*, 1999 WL 495126, at *5, *9 (N.D. Ill. July 1, 1999) (holding statements on Gerber baby food packaging were puffery and not actionable under Illinois consumer protection act). They are not "a specific, measurable claim that can be reasonably interpreted as an objective fact." *Intertape Polymer Corp. v. Inspired Tech., Inc.*, 725 F. Supp. 2d 1319, 1335 (M.D. Fla. 2010). For example, statements asserting that one is better than its competitor constitute mere "puffing," and are not actionable as false advertising. *Fla. Breckenridge, Inc. v. Solvay Pharm., Inc.*, 97-8417-CIV, 1998 WL 468753, at *9 (S.D. Fla. Mar. 18, 1998) (citing *Nikkal Indus., Ltd. v. Salton, Inc.*, 735 F. Supp. 1227, 1234, n.3 (S.D.N.Y. 1990)). *See also Intertape Polymer*, 725 F. Supp. 2d at 1335 (even if express statements convey implied message that product's efficacy is "better than" another product's efficacy, statement is not "measurable claim that can be reasonably interpreted as an objective fact and is therefore puffery"); *American Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1292 (11th Cir. 2010) (affirming dismissal of complaint in part due to allegations against non-actionable puffery in RICO action predicated on fraud). Stated another way:

> [A] seller's general claims that its product or service is "better" than another—or even "the best"—simply are not misrepresentations of material fact. The seller is merely boasting or expressing a general opinion upon which, in itself, no buyer can reasonably rely.

Scott v. Dixie Homecrafters, 125 F. Supp. 2d 1311, 1314 (M.D. Ala. 2000) (interpreting Alabama law). Whether a statement is puffery or a statement of fact as a matter of law and thus can be resolved in a motion to dismiss. *See Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1053 (9th Cir. 2008).

Even assuming Colgate's express claims can be interpreted to imply Softsoap Antibacterial is "better" or "more effective" than other soaps, such implied claims are inactionable puffery because the implications are nothing more than vague assertions of superiority, similar to Colgate's alleged express statements of puffery. *See, e.g., In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604, at *13-*14 (D.N.J. July 10, 2009) (holding marketing saying product was an effective treatment, even though no clinical data to support claim, was inactionable because "marketing of this sort is commonly referred to as 'puffery'"). Plaintiffs contend Colgate's "implied representations . . . induce consumers into purchasing Softsoap," that "Softsoap Antibacterial will destroy more bacteria than ordinary hand soap," that the active ingredient implies that Softsoap "[outperforms] other soap products," and that Softsoap is "more effective" and "superior in quality." (Compl. ¶¶ 11, 51, 58, 78, 84.) These alleged implications are no different than express statements stating that one product is better than its competitors—such as "far brighter than any lamp ever before offered for home movies," "the beam floods an area greater than the coverage of the widest wide angle lens,"—which courts have held to be puffery. *See Smith-Victor Corp. v. Sylvania Elec. Prod. Inc.*, 242 F. Supp. 302, 308 (N.D. Ill. 1965) (holding puffery not actionable under Lanham Act); *Intertape*, 725 F. Supp. 2d at 1335. Accordingly, an implied claim consisting of mere puffery must fail. *See also Barbara's Sales*, 879 N.E.2d at 927 (Ill. 2007) (noting that the name "Pentium IV" implies it is better than Pentium III is a vague suggestion constituting puffery under Illinois consumer-protection law).

Second, plaintiffs have alleged no facts that support their assertion that consumers would reasonably construe Colgate's marketing statements to imply that Softsoap Antibacterial is better than regular soap. Plaintiffs must show that a "reasonable consumer" would construe the explicit

claims as making such an implication. *See, e.g., Hill v. Roll Intern. Corp.*, 195 Cal. App. 4th 1295, 1304 (Cal. Ct. App. 2011) (finding that representation on water bottles did not convey false message to reasonable consumers). For example, plaintiffs allege that express claims such as kills "99% of germs," "antibacterial," "America's most trusted handsoap" or "Dermatologist tested" or even "Goodbye Germs – Hello World" imply that the product will destroy more bacteria or be more effective than regular hand soap. (Compl. ¶¶ 2, 51, 52, 56, 57.) However, plaintiffs fail to allege how a reasonable consumer would plausibly view these claims and conclude that Softsoap Antibacterial is more effective than ordinary soap and water.

Plaintiffs further fail to allege any comparison, implied or express, that Colgate has made between Softsoap Antibacterial and conventional or ordinary soap and water. Nowhere do the alleged marketing statements reference regular soap and water, nor do they compare any other product. Thus, plaintiff does not allege sufficient facts to allow the Court to plausibly conclude Colgate made representations that were "likely to mislead the consumer acting reasonably in the circumstances" into thinking that Softsoap Antibacterial soap was more effective than conventional soaps or into purchasing the product on that basis. *Zlotnick v. Premier Sales Group*, Inc., 480 F.3d 1281, 1284–87 (11th Cir. 2007) (dismissing complaint under Florida consumer protection law because defendant's actions would not mislead reasonable consumer); *Hill*, 195 Cal. App. 4th at 1304 (dismissing suit because packaging did not mislead reasonable consumer); *Tylka*, 1999 WL 495126, at *6 (stating central question under consumer protection act is whether advertising would mislead "reasonable consumers").

Accordingly, plaintiffs will also be unable to satisfy the causation element under any of the state consumer laws. The Complaint does not establish a causal connection between the alleged implication and consumers' purchases; simply alleging the conclusion that the statements

were material (*e.g.* Compl. ¶¶ 86, 118) is insufficient for pleading purposes. *See, e.g., Costa v. Kerzner Intern. Resorts, Inc.*, 2011 WL 2519244, at *2 (S.D. Fla. June 23, 2011) (concluding that plaintiff failed to plead a "material misrepresentation"); *Marolda v. Symantec Corp.*, 672 F.Supp.2d 992, 1001 (N.D. Cal. 2009) (noting that plaintiff's conclusory and vague statements failed to show what effect alleged misrepresentations had on plaintiff's decisions); *New Jersey Citizen Action v. Schering-Plough Corp.*, 842 A.2d 174, 178 (N.J. Sup. Ct. 2003) (plaintiffs must plead and demonstrate causal nexus between alleged deception and damages sustained).

B. The Express Statements Do Not Support Any Of Plaintiffs' Purported Claims

The Complaint also challenges express statements that appeared on some Softsoap Antibacterial packaging, specifically the mere use of the term "antibacterial," that the product "is clinically proven to eliminate 99% of the germs your family encounters" and "eliminates 99% of germs." (Compl. ¶¶ 2, 51-56, 59.)

Much like their allegations relating to the allegedly implied claim, plaintiffs fail to allege how any of the express statements are actually, or even plausibly, false.[19] Instead, each allegation regarding the express statements points back to the alleged *implied* statement that Softsoap Antibacterial is better than ordinary soap. For example, plaintiffs do not allege that Softsoap Antibacterial is not "antibacterial." Instead, plaintiffs allege only that the "antibacterial" name creates the misleading *implication* that the product will destroy more

[19] Instead of falsity, plaintiffs focus on the argument that the claims lacked substantiation. (Compl. ¶¶ 3, 7, 8, 48, 51, 59, 65-66, 73, 79, 80, 82, 84(d), (f).) This, however, is insufficient to state a claim. *Loreto v. Procter & Gamble Co.*, 737 F. Supp. 2d 909, 920 (S.D. Ohio 2010 ("to prevail on a claim that defendant misrepresented the effectiveness of its product, plaintiffs must show that the alleged misrepresentations are 'false or misleading, not merely that they are unsubstantiated by acceptable tests or other proof'"); *Chavez*, No. 09-cv-09192 (C.D. Cal. Jan. 10, 2011) (lack of substantiation claims do not support false advertising cause of action).

bacteria than ordinary hand soap.[20] (Compl. ¶ 16.) Similarly, plaintiff does not contend Softsoap Antibacterial has not been "dermatologist tested." Instead, they allege the "dermatologist tested" claim *leads consumers to believe* Softsoap Antibacterial has special health benefits over ordinary liquid hand soap.[21] (*Id*. ¶¶ 82-83.)

Although the Complaint conclusorily asserts that Colgate's efficacy claims, such as "kills 99% of germs" or "clinically proven to eliminate 99% of the germs your family encounters" are "false" or "deceptive" (*id*. ¶¶ 2, 53), it lacks any factual allegations to support these conclusory statements. For example, the Complaint neither references any report that indicates Softsoap Antibacterial hand soap does not eliminate 99% of the germs a family encounters, nor cites any study that purportedly shows Softsoap Antibacterial fails to kill 99% of germs. These conclusory allegations "are not entitled to the presumption of truth." *Iqbal*, 129 S.Ct. at 1950; *see also Wallace v. Garside*, 2010 WL 5798655, at *3 (S.D. Ga. Dec. 23, 2010) (granting motion to dismiss where plaintiff made only conclusory allegations such as "false reports," "false statements," and "false materials"); *Tylka*, 1999 WL 495126, at *9 (finding that ads representing that Gerber "conducted extensive consumer tests" were inactionable since there was "no assertion that the statistics were falsified").[22] Again, plaintiffs cite these statements to contend

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[20] Meanwhile, the use of the term "antibacterial" itself is not even actionable because the FDA has expressed the view that a product that includes triclosan must be labeled "antibacterial." *See* 43 Fed. Reg. 1210 (discussing triclosan and its use in soaps; "[t]he labeling of the product shall contain the established name of the drug, if any, and shall identify the product as either an 'antimicrobial soap' or 'antibacterial soap'").

[21] Plaintiff also raises issue with statements such as "Goodbye germs. Hello world" and that Softsoap is "America's most trusted [antibacterial] hand soap." (*Id.* ¶¶ 2, 56-57.) No reasonable consumer would interpret these allegations as implying Softsoap Antibacterial is better than regular hand soap. For the reasons explained above, these unquantifiable and subjective statements are also mere puffery and therefore not actionable.

[22] Although plaintiffs do not explicitly allege a fraud claim, they liberally make fraud allegations without providing the particularity required to support them. (*See, e.g.*, Compl. ¶ 137 (describing Colgate's "deceptive, *fraudulent*, and misleading packaging, advertising, marketing,

Colgate's marketing campaign implied "the unmistakably clear, but unconscionably deceptive and unfair message, that Softsoap Antibacterial is more effective at eliminating germs, protecting the consumer from germs, and thus preventing illness and promoting good health, than washing with ordinary liquid hand soaps." (Compl. ¶ 61.) Thus, all roads lead back to the implied claim, which is fundamentally flawed for the reasons stated above.

Moreover, plaintiffs' allegations based on Colgate's statements—including "Goodbye germs. Hello world," and "America's most trusted handsoap" as well as others (Compl. ¶¶ 2, 55-57, 82)—are puffery (as discussed *supra* § III.A.2) because they offer nothing more than general and vague claims of superiority. *Stiffel Co. v. Westwood Lighting Grp.*, 658 F. Supp. 1103, 1115 (D.N.J. 1987) ("advertising the advantages of a product, including claims of general superiority, constitutes puffing and is not actionable as false advertising"). No matter how much plaintiffs may dislike Colgate's advertising claims, general and vague assertions such as "America's most trusted handsoap" are merely expressions of opinion, upon which no reasonable consumer could rely. Plaintiffs' claims that rely on such puffery must fail.

C. Plaintiffs' Breach Of Implied Warranty Claim Must Fail

To allege a cause of action under breach of implied warranty, plaintiffs must allege that Colgate sold goods that were not merchantable at the time of sale or not fit for the ordinary or

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and sales" (emphasis added)).) Plaintiffs have generally identified eight alleged statements along with several implied statements concerning Softsoap Antibacterial as "deceptive and misleading." However, not one of the named plaintiffs alleges what specific representations he or she saw. (*Id.* ¶¶ 17-25.) Nor do they allege when or where they saw "those" claims. (*Id.*) In fact, other than putting quotation marks around the alleged statements, plaintiffs have provided very few allegations concerning the extent to which those allegations were relied upon. Also missing is any allegation of when several of the plaintiffs purchased the product; instead, many only allege that they purchased the product "over the last several years." (*Id.*) Because their claims sound in fraud, but the Complaint fails to sustain any claim for fraud under Fed. R. Civ. P. 9(b), *see Ziemba v. Cascade Int'l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001), such fraud or related allegations should be stricken from the Complaint.

particular purpose for which they are designed or used. *See McLeod v. W. S. Merrell Co., Division of Richardson-Merrell, Inc*., 174 So.2d 736, 738 (Fla. 1965); *Waterfall Homeowners Ass'n v. Viega, Inc*., 2012 WL 2838565, at *9 (D. Nev. July 10, 2012); *Tomek v. Apple, Inc*., 2012 WL 2857035, at *6-*7 (E.D. Cal. July 11, 2012); S.C. Code Ann. § 36-2-315; *Pappalardo v. Combat Sports, Inc*., 2011 WL 6756949, at *8 (D.N.J. Dec. 23, 2011). The implied warranty does not "impose a general requirement that goods precisely fulfill the expectation of the buyer. Instead, it provides for a minimum level of quality." *Hughes v. Panasonic*, 2011 WL 2976839, at * 22 (D.N.J. July 21, 2011) (quoting *Berenblat v. Apple, Inc*., 2009 WL 2591366, at *3 (N.D. Cal. Aug. 21, 2009)). The warranty "simply means that the thing sold is reasonably fit for the *general purpose* for which it is manufactured and sold." *Ferrari v. American Honda Motor Co., Inc*., 2009 WL 211702, at *3 (N.J. Ct. App. Jan. 30, 2009) (emphasis added). Accordingly, courts typically find goods to be unfit for their ordinary purposes "when they can identify one of three general types of defects: manufacturing defects, design defects, and failure to give the buyer proper instructions with respect to the goods." Barkley Clark & Christopher Smith, THE LAW OF PRODUCT WARRANTIES § 5.5 (2010).

Softsoap Antibacterial was clearly manufactured as a consumer liquid hand soap. The Complaint does not allege that the general purpose of Softsoap Antibacterial was anything other than to wash hands and kill bacteria. Plaintiffs thus fail to allege why the product was not merchantable as a hand soap or not fit for the purpose of eliminating bacteria. Instead, plaintiffs merely allege conclusory statements that Colgate warranted that the product was "of merchantable quality and fit for the use for which it was intended" (Compl. ¶¶ 127-128), without further discussion of the facts that might support such conclusions.

Furthermore, as discussed above, plaintiff has failed to adequately plead privity to qualify for relief under a breach of warranty claim under Florida law, and as such, any breach of implied warranty claim brought by the Florida subclass of the "Breach of Implied Warranty Plaintiffs" should be dismissed. *Jovine v. Abbott Laboratories, Inc*., 795 F.Supp.2d 1331, 1340 (S.D. Fla. 2011) ("[P]ursuant to Florida law, 'a plaintiff cannot recover economic losses for breach of implied warranty in the absence of privity.'")

D. The Court Should Dismiss The Unjust Enrichment Claim

Based on the same underlying facts and allegations as its other defective theories, plaintiffs' unjust enrichment claim is likewise fatally flawed. (Compl. ¶¶ 134-139.) Plaintiff fails to state a claim for unjust enrichment for several reasons.

1. Existence Of An Alleged Contract Voids Unjust Enrichment Claims

Plaintiffs cannot state a claim for the equitable remedy of unjust enrichment where there is an adequate remedy at law. Plaintiffs assert that each member of the "Breach of Express Warranty States Class" "formed a contract with Colgate at the time they purchased Softsoap Antibacterial products" and that the contract terms include "promises and affirmations of fact." (Compl. ¶¶ 117, 119.) As plaintiffs' "Breach of Express Warranty States Class" encompasses all the relevant states, allegation of contract claims preclude all these plaintiffs from pursing a claim under unjust enrichment. *Prignano v. Prignano*, 934 N.E.2d 89, 108 (Ill. App. Div. 2010); *see also Shaw v. Hyatt Int'l Corp.*, 461 F.3d 899, 902 (7th Cir. 2006) (affirming 12(b)(6) dismissal of unjust enrichment based on principle that unjust enrichment is unavailable where claim rests on breach of contract); *Amer. Honda Motor Co., Inc. v. Motorcycle Information Network, Inc.*, 390 F. Supp. 2d 1170, 1178 (M.D. Fla. 2005) ("to properly state a claim for unjust enrichment, a party must allege that no adequate legal remedy exists"; dismissing unjust enrichment claim because adequate remedy existed at law); *Martinez v. Weyerhaeuser Mortg. Co*., 959 F. Supp.

1511, 1518-19 (S.D. Fla. 1996).

Indeed, plaintiffs' factual allegations supporting its unjust enrichment claim are indistinguishable from those alleged under their contract claims. *See, e.g., Guinn v. Hoskins Chevrolet*, 836 N.E.2d 681, 704 (Ill. App. Div. 2005) (noting that while plaintiff can plead contract and unjust enrichment in the alternative, claims for unjust enrichment were properly dismissed because her unjust enrichment claims solely depends on the same allegations as her contract claims). In support of the Unjust Enrichment Count, plaintiffs have alleged that Colgate was enriched due to its deceptive advertising and marketing. (Compl. ¶ 137.) In the Breach of Express Warranty Count, plaintiffs similarly relied on Colgate's marketing and advertising as the basis constituting express warranties. (Compl. ¶ 117.) Because the alleged benefits conferred upon Colgate, as well as other factual allegations, are exactly same under both counts, the unjust enrichment claims cannot stand. *See, e.g., Bosland v. Warnock Dodge, Inc.*, A.2d 942, 950 (N.J. App. Div. 2007) (affirming lower court's dismissal of unjust enrichment because there was no benefit conferred upon defendant that was separate and distinct from the written contract).

2. The New Jersey Plaintiffs Cannot State A Claim For Unjust Enrichment In The Absence Of A Direct Relationship

Plaintiffs' unjust enrichment claims under New Jersey law are particularly infirm. Under New Jersey law, a plaintiff must allege a direct relationship with the defendant to support an unjust enrichment claim. *See Snyder v. Farnam Co., Inc.*, 792 F. Supp. 2d 712, 724 (D.N.J. 2011). An unjust enrichment claim requires plaintiff to allege "(1) at plaintiff's expense (2) defendant received benefit (3) under circumstances that would make it unjust for defendant to retain benefit without paying for it." *Maniscalco v. Brother Int'l Corp. (USA)*, 627 F. Supp. 2d 494, 505 (D.N.J. 2009). Further, "[t]he unjust enrichment doctrine requires that plaintiff show that it expected remuneration from the defendant at the time it performed or conferred a benefit

on defendant and that the failure of remuneration enriched defendant beyond its contractual rights." *Id.* New Jersey courts have interpreted the element of conferring a benefit on the defendant to require that "the plaintiff allege a sufficiently direct relationship with the defendant to support the claim." *Snyder*, 792 F. Supp. 2d at 724. In *Snyder*, the court held that buying flea and tick treatment from retailers did not confer a direct benefit on the manufacturers of those products. *Id.* (dismissing the unjust enrichment claims because the "Plaintiffs are alleging that they are unsatisfied with purchases from retailers, yet they want their money returned by the manufacturer"). Similarly, the court in *Cooper v. Samsung Electronics. America, Inc.* denied plaintiff's unjust enrichment claims because the plaintiff bought the television from a retailer and not from Samsung. 2008 WL 4513924, at *10 (D.N.J. Sept. 30, 2008), *aff'd*, 374 F. App'x 250 (3d Cir. 2010) (finding that there can be no unjust enrichment claims if there is no relationship conferring any direct benefit on Samsung through Cooper's purchase). Accordingly, if a plaintiff purchases a product from a retailer and not directly from a defendant, this type of transaction fails the requirement of direction relationship under New Jersey law.

Because plaintiffs bought the products from retailers and not from Colgate, they do not have a sufficiently direct relationship with Colgate. The facts of plaintiffs' allegations are no different from those asserted by the plaintiffs in *Snyder* and *Cooper*, in which the courts held that retail transactions by themselves cannot give rise to unjust enrichment claims. (Compl. ¶¶ 17-25.) Accordingly, this Court should dismiss New Jersey plaintiffs' unjust enrichment claims.

E. Injunctive Relief is Not a Cause of Action and Should Be Dismissed

Finally, this Court should dismiss Count V for injunctive relief because injunctive relief is an equitable remedy and not an independent cause of action. *Maine Educ. Ass'n Benefits Trust v. Cioppa*, 1:11-CV-381-GZS, 2012 WL 363923, at *1 (D. Me. Feb. 3, 2012). Hence, the claim for injunctive relief can succeed only if the plaintiffs have stated a valid cause of action in

support of such relief. *See Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 115 (1st Cir. 2003) ("Injunctive relief, of course, is available only if the plaintiffs have stated a valid cause of action; otherwise, there is no probability of success).

Further, plaintiffs have pleaded only monetary harms and no actual health harm. (Compl. ¶¶ 5, 8, 11, 78, 80.) Plaintiffs concede they have a legal remedy. (Compl. ¶¶ 112 (stating plaintiffs "entitled to a full or partial refund as allowed under each of the several state laws"); 121 (alleging plaintiffs were "damaged in the amount of the purchase price they paid for Softsoap Antibacterial products, in an aggregate amount to be proven at trial"); Request for Relief ¶ B (requesting "economic, monetary, actual damages (including multiple damages), consequential, compensatory, or statutory damages, whichever is greater").) Where a legal remedy is available, an equitable remedy is improper and this Court should dismiss the claim for injunctive relief. *Cioppa*, 2012 WL 363923, at *1 (the Court must "bear constantly in mind that an injunction is an equitable remedy which should not be lightly indulged in, but used sparingly and only in a clear and plain case").

Conclusion

For the foregoing reasons, Colgate respectfully requests that the Court dismiss plaintiffs' Complaint.

Dated: August 10, 2012

Respectfully submitted,

/s/ Shon Morgan

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CERTIFICATE OF SERVICE

I hereby certify that, on August 10, 2012, a true and correct copy of the foregoing document was filed with the Court's CM/ECF system, which will provide email notification to counsel of record.

Dated: August 10, 2012 /s/ *Melissa N. Chan*